

Polk State College Procedure

Subject	Reference	Date	Number
Institutional Review Board (IRB)		02/04/2020	5032

I. Purpose

Polk State College encourages and supports the scholarly endeavors of its students, faculty, and staff, as well as other educational institutions and individuals. The College's pursuit of scholarly research often requires involvement of human subjects for data collection and analyses. In conducting research involving human subjects, the purpose of the Institutional Review Board (IRB), is to ensure both in advance and by periodic review that the rights and welfare of subjects are protected and the risks are considered and minimized. For such research, all human subject participation must be voluntary, and subjects must be provided with a legally effective process for informed consent. Lastly, all research must be conducted in an ethical manner and in compliance with established standards. To safeguard individuals (e.g., students, employees, and community members) who participate in research projects involving human subjects, the College has established an Institutional Review Board (IRB) in accordance with applicable federal, state, and local laws regarding the protection of human subjects in research.

II. Process

- A. Polk State College supports research and grant-based projects that are integral to carrying out its mission. An individual who proposes to conduct human research at Polk State College must follow the IRB's *Human Research Protection Procedure* and submit an *Institutional Review Board Research Protocol Submission Form* for approval. Both of these forms, as well as additional support materials, are available through the College's IRB website.
- B. Research approval requests are submitted to the Polk State College IRB Chair, who then coordinates the review process. The IRB's composition is published as part of the College's *Standing Committees* listing.
- C. Polk State College's IRB has the authority to:
 1. Approve or disapprove all human-subject research conducted within the organization.
 2. Defer to the results of the IRB process at the institution where the human-subject research originates (when appropriate).

3. Determine if the proposed research study meets the definition of “exempt-from-review.”
 4. Suspend or terminate research that is not conducted in accordance with regulations, statutes, principles, or IRB requirements, or that has been associated with unexpected, serious harm to subjects.
- D. Research that has been approved by the College’s IRB may be subject to further appropriate review and disapproval by officials of the institution; however, those officials may not approve the research if the College’s IRB has disapproved it (per federal regulations *45 CFR 46.112* and *21 CFR 56.112*).
- E. Each year, the IRB provides a report to the President’s Staff membership that includes a review of the progress and outcomes of the IRB.

Note: *A person under the age of 18 is unable to give informed consent and cannot participate in human-subject research without consent from a parent or legal guardian.*

III. Definitions

The definitions in this document have been taken from the U.S. Department of Health and Human Services Office for Human Research Protections, and the *Code of Federal Regulations* (CFR) (2009) (Retrieved from: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.102>).

- A. **Human Subject:** Polk State College defines a human subject as ‘a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information.’
- B. **Research:** The College defines research as ‘a systematic investigation, testing, or evaluation that is designed to develop or contribute to generalizable knowledge.’ Activities that meet this definition constitute research for the purposes of this policy, whether or not they are conducted or supported under a program that is considered research-based for other purposes.
- C. **Exempt-from-Review** – Research that is exempt-from-review includes studies conducted in established or commonly accepted educational settings such as a classroom. In classes, students may be assigned to conduct interviews, distribute questionnaires, or engage in participant observations. If the purpose of these activities is solely pedagogical and is not designed to contribute to a body of knowledge, the activities do not meet the federal definition of “research with human subjects.” Classroom research, however, must be supervised by a faculty member; cannot include research subjects under the age of 18; and should not involve sensitive, personal, or incriminating topics. As such, these types of

projects do not require formal IRB approval and thus may not be presented at local, state, national, or international conferences; be published; or be used for thesis or dissertation projects. If a student-researcher believes that he or she may (at some later time) wish to present or publish his or her work, the student must, with the assistance of a faculty member, seek approval from a properly constituted IRB that meets federal regulations, and follow the steps of approval for College affiliated researchers.

History: Adopted: February 22, 2013

Revised: February 4, 2020

<i>Mary C. Clark</i>	12/8/21	<i>Mary C. Clark</i>	12/8/2021
Executive Responsible for Procedure	Date	President's Staff Member's Approval	Date
<i>Angela M. Falconetti</i>			12/8/2021
President's Approval			Date